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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,266	10/685,266 10/14/2003		Yoshiyuki Tatsumi	700938-052220-DIV	4026
53143	7590	03/10/2006		EXAMINER	
RONALD	I. EISEN	STEIN	SRIVASTAVA, KAILASH C		
NIXON PE 100 SUMM		<del></del>	ART UNIT	PAPER NUMBER	
BOSTON,		<del></del>	1655		

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/685,266	TATSUMI ET AL				
	Office Action Summary	Examiner	Art Unit .				
		Dr. Kailash C. Srivastava	1655				
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address				
WHIC - Exter after - If NO - Failui Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATES of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period vere to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	N.  lely filed  the mailing date of this communication.  D (35 U.S.C. § 133).				
Status		•					
1)[X]	Responsive to communication(s) filed on 14 O	ctober 2003.					
•	•	action is non-final.					
,—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)⊠ Claim(s) <u>1 and 18-20</u> is/are pending in the application.							
-	4a) Of the above claim(s) is/are withdrawn from consideration.						
	5) Claim(s) is/are allowed.						
,							
·	Claim(s) is/are objected to.						
•	Claim(s) 1 and 18-20 are subject to restriction	and/or election requirement.	* .				
, —	on Papers						
	The specification is objected to by the Examine	r					
9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on is/are: a)  accepted or b)  objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
,—	ınder 35 U.S.C. § 119						
_	•	priority under 35 U.S.C. § 119(a)	-(d) or (f).				
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:						
u),	1. ☐ Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
	3. Copies of the certified copies of the prior						
	application from the International Bureau	*	<b>.</b>				
* See the attached detailed Office action for a list of the certified copies not received.							
		·					
Attachmen		<b>∆</b> □ (	(DTO 442)				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da					
3) 🔲 Inform	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date		atent Application (PTO-152)				

#### **DETAILED ACTION**

- 1. Applicants' Preliminary amendment filed 14 October 2003 is acknowledged and entered.
- 2. Applicants to note that the correct Serial Number of your Application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/685,266; not Divisional of 10/031,929 as recited in the Preliminary Amendment filed 14 October 2003. Please ensure that the correct U.S. Serial Number (i.e., 10/685,266) for this application is cited in all future correspondence with this Office.
- 3. Your application under prosecution at the USPTO is assigned to Dr. Kailash C. Srivastava in Art Unit 1655. To aid in correlating any papers for this application (i.e., USSN 10/685,266), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

#### **Claims Status**

- 4. Claims 2-17 have been cancelled.
- 5. Claims 18-20 have been added.
- 6. Claims 1 and 18-20 are pending.

### Restriction/Election

- 7. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Group I, consisting of claim 1drawn to a method to identify a pathogenic microorganism, classified under Class 436, subclass 63, for example.
  - Group II, consisting of claims 18-20, drawn to a method to treat an individual having onychomycosis via administering an antifungal compound to said individual, classified under Class 424, subclass 404, for example.

## **Inventions are Independent and Distinct**

8. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-II are unrelated to each other because each one of them is

directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claim encompassed in Group I is directed to a method to identify a microorganism whereas those in Group II is to treat an individual having onychomycosis. Thus, invention in Group I is a diagnostic method, while the method in Group II invention is a treatment method. Therefore, the methods claimed in inventions I-II, encompassing Claims 1 and 18-20 respectively will not be practiced together.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- II in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

9. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR §1.143). An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after

the election, applicant must indicate which claims are readable upon the elected claims/ species [MPEP § 809.02(a)].

- 10. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(l).
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.

Patent Examiner Art Unit <u>1655</u> (571) 272-0923

March 5, 2006

RALPH GITOMER

PRIMARY EXAMINER
GROUP 1200